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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,034	01/31/2007	David Bassin	3869/029 US	1908

22440 7590 03/18/2010

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EXAMINER	
LOUIS, LATOYA M	

ART UNIT	PAPER NUMBER
3771	

MAIL DATE	DELIVERY MODE
03/18/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/596,034	BASSIN, DAVID	
	Examiner	Art Unit	
	LATOYA LOUIS	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 January 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *112-134* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *112-134* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This office action is responsive to the amendment filed 1/12/2010. No claims were added or amended. Thus, claims 112-134 are pending.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 112-114 and 121 are rejected under 35 U.S.C. 102(b) as being anticipated by Cotner et al. US Pat. No. 5, 645, 054.

Regarding claim 112, Cotner et al. teaches in fig. 1 an apparatus for providing ventilatory assistance to a patient comprising: a control mechanism (10) for deriving two error signals (col. 6 lines 65-67-col. 7 lines 1-14, col. 9 lines 25-35 disclose the timing circuit 27 which indicates when there has been no normal inhalation for 8 seconds as first error signal. Note that the term "logical one" represents normal inhalation. Col. 6 lines 56-64, col. 8 lines 11-26, and col. 8 lines 42-60 disclose critical flow limitations as second error signal which are false inhalation indications sensed by flow sensor 28 and eliminated by antifalsing circuit 17) each of which is a function of the same target value (normal inhalation as target value) (col. 9 lines 25-35 describes that the first error signal is a function of normal inhalation as target value because it determines when there has been no normal inhalation for 8 seconds and then causes a ventilator response. Col. 8 lines 42-60 disclose that the second error signal indicates false inhalation, or lack of normal inhalation as target value, and thus is also related to normal inhalation and ventilator

response) and a respective one of two patient ventilation measures (col. 6 lines 44-67 disclose that the error signals are derived from, dependent on, and thus are a function of the output of flow sensor 28 and output of dynamic reference circuit 25 as two ventilation measures), the two patient ventilation measures having respective relatively fast and relatively slow speeds of response (col. 6 lines 13-30 disclose that the output of the flow sensor 28 has a relatively fast response compared with output "R" of dynamic reference circuit 25. Likewise output "R" of dynamic reference circuit 25 has a relatively slow response in comparison with the output of flow signal 25) said control mechanism (10) further deriving two control responses (from unit 38) to respective ones of said two error signals (col. 9 lines 41-48 and col. 9 lines 7-25 disclose that the control response of unit 38 to the first error signal is to increase the blower speed up to 20cm of water or until normal inhalation is reached. Col. 9 lines 64-67-col. 10 lines 1-2, col. 9 lines 12-18 disclose that the control response of unit 38 to the second error signal, represented by letter "C" in fig. 3, is to keep the blower speed at 2.5cm of water until the first error signal is detected at letter "D") and combining said two control responses to produce an overall control response (the overall response of the blower unit 38) that increasingly favors the control response (increasing blower speed) to the error signal (output of timing circuit 27) that is a function of the ventilation measure with the faster speed of response (output of flow sensor 28) over the control response (maintaining base speed 2.5) to the error signal (critical flow) that is a function of the ventilation measure with the slower speed of response ("R") as the ventilation measure with the faster speed of response (output of flow sensor 28) becomes increasingly less than said target value (col. 8 lines 11-25, col. 9 lines 7-24, and fig. 3 with col. 9 lines 64-67-col. 10 lines 1-3 and figs. 2A-2C disclose that as the output of the flow sensor curve represented by letter "M" in fig.

2A increasingly fails to meet normal inhalation as target value as time increases by not decreasing below "R" through the end of period "Y" representing 8 seconds, the blower unit's overall response is to increase blower speed thereby favoring the same control response of the first error signal represented by the output of timing circuit 27.); and a ventilator (blow unit 12) responsive to said overall control response for controlling the pressure of air delivered to said patient (col. 9 lines 42-48, col. 5 lines 40-49).

Regarding claim 113, Cotner et al. discloses that each of said two control responses is a function of the amplitude and sign of the respective one of said error signals (col. 9 lines 33-35, col. 8 lines 65-67-col. 9 lines1-3 teaches that both of the control responses are dependent on whether the timing circuit has an increasing amplitude up to a positive value of 8 sec. or not, or alternatively, whether the timing circuit has a positive increasing sign up to a high amplitude of 8 seconds or not) so that the control response to the error signal that is a function of the ventilation measure with the faster speed of response (increasing blower speed) is more vigorous than the control response to the error signal that is a function of the ventilation measure with the slower speed of response (maintaining base blower speed). (col. 9 lines 41-44 discloses that the blower can increase speed from 2.5 to the max speed of 20cm water in as little as 2 seconds. Fig. 3C and col. 9 lines 64-67-col. 10 lines 1-2, col. 9 lines 12-13 disclose that the blower speed is maintained during normal inhalation and for 8 seconds after critical flow is detected as disclosed in. Therefore, the control response of increasing blower speed is more vigorous).

Regarding claims 114 and 121 Cotner et al. teaches in fig. 3 that the degree of control exercised by said ventilator (blow unit 12:fig. 1) increases with the magnitudes of said two error signals (when the second error signal indicates the onset of critical flow at "C" and the first error

signal increases to 8 seconds represented at "D", the response of the blower unit as ventilator is to increase ventilation pressure up to a max represented by "I").

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 115, 122, 125, and 128-134 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cotner et al. in view of Berthon-Jones US Pat. No. 6, 951, 217 B2 hereinafter Berthon-Jones '217.

Regarding claim 125, Cotner teaches a control mechanism (36) for determining when an inspiration and an expiration phase is occurring (col. 6 lines 43-48 and fig. 2A) but does not specifically disclose that the control mechanism determines the phase of the current breathing cycle and adjusts said overall control response to be a function of the amplitude at the determined phase of the current breathing cycle of an amplitude-versus-phase template that is appropriate for a normal breathing cycle. However, Berthon-Jones '217 teaches in fig. 2 that the control mechanism (16) determines the phase of the current breathing cycle (col. 9 lines 38-40) and adjusts said overall control response (the amount of pressure delivered "Pmask" as control response seen in the formula on col. 9 line 43) to be a function of the amplitude at the determined phase of the current breathing cycle (col. 9 line 43 shows Pmask to be a function of amplitude A multiplied by the current phase) of an amplitude-versus-phase template that is appropriate for a

normal breathing cycle (fig. 3. and col. 9 lines 40-41, 48-57. See also the relationship of relationship of A in col. 9 line 18). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the control mechanism of Cotner with the function of determining the phase to control the ventilator response as taught by Berthon-Jones '217 to provide a more comfortable and safe ventilation response that cycles with the patient's respiratory cycle.

Regarding claim 128, Cotner et al. discloses error signals related to patient ventilation and target value (fig. 2A) but does not disclose that each of said error signals is a clipped integral of the respective patient ventilation measure minus said target value. However, Berthon-Jones '217 teaches that each of said error signals is a clipped integral of the respective patient ventilation measure minus said target value (the error signal is defined as the ventilation measure minus the target value. Therefore as shown in the formula of the disclosure in col. 9 lines 6-22 the error signal is being taken as a clipped integral). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the error signal of Cotner et al. with the clipped integral as taught by Berthon-Jones '217 to provide a convenient range to operate the ventilator pressure.

Regarding claim 129, Cotner et al. discloses a responsive ventilator (col. 9 lines 25-35) but does not specifically disclose that the ventilator includes a servo control mechanism whose gain is adjusted in accordance with the magnitudes of said error signals. However, Berthon-Jones '217 teaches that the ventilator (fig. 2) includes a servo control mechanism (19) whose gain is adjusted in accordance with the magnitudes of said error signals (col. 9 line 18 and in col. 9 lines 6-28 discloses that the ventilator pressure amplitude A as gain or alternatively the servo

controller's gain G is adjusted in proportion to the error signals e as shown in the formula. See also the formula deriving mask pressure in col. 9 lines 38-47 which shows relationship with A which is related to e and G. See also col. 8 lines 53-67, col. 7 lines 57-63). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the ventilator of Cotner et al. with the features of the servo controller gain adjustment as taught by Berthon-Jones '217 to provide a closed loop feedback mechanism to provide a more efficient means of correcting ventilation errors.

Regarding claim 130, the modified Cotner invention teaches that the gain increases with the magnitudes of the error signals (col. 9 line 18 and in col. 9 lines 6-28, col. 9 lines 38-47, col. 8 lines 40-67, col. 7 lines 57-63 of Berthon-Jones '217 teaches that the ventilator pressure amplitude A as gain or alternatively the servo controller's gain G is increased in proportion to an increase in error signals e.

Regarding claims 115, 122, and 131 the modified Cotner invention discloses that for equal error signals (col. 9 lines 9-25 of Berthon-Jones '217) below and above said target value (col. 8 lines 35-39 of Berthon-Jones '217), the degree of control exercised by said ventilator is greater for error signals below said target value (col. 10 lines 63-67-col. 11 lines 1-7 of Berthon-Jones '217 teaches that since error signals are only 95% of actual flow, error signals will be generated when ventilatory support is added to the patients attempts at breathing. Therefore, the ventilator support will remain at 3 cm water and there will be no change of ventilatory support. However, col. 11 lines 7-13, and fig. 6 with col. 11 lines 30-47 discloses that if the error signal drops below the target ventilation, the ventilator quickly increases pressure to a maximum of 10

cm water to bring airflow back up to 95% of the previous actual ventilation. See also fig. 5 showing difference between target and average ventilation).

Regarding claim 132, the modified Cotner invention discloses that gain is varied more aggressively for conditions of hypoventilation than for conditions of hyperventilation (col. 10 lines 63-67-col. 11 lines 1-7 of Berthon-Jones '217 discloses that when ventilatory support is added to the patient's attempts at breathing, the patient's actual flow exceeds the target which is only 95% of actual flow and thus the patient is hyperventilated. As shown, the ventilator support will remain at 3cm water for this type of hyperventilation and there will be no change of ventilatory support. However, as taught in col. 11 lines 7-13, and fig. 6 with col. 11 lines 30-47 of Berthon-Jones '217, if the error signal drops below the target ventilation, the ventilator quickly increases pressure to a maximum of 10cm water to bring airflow back up to 95% of the previous actual ventilation. See also fig. 5 showing difference between target and average ventilation.

Regarding claim 133, the modified Cotner invention teaches that the ventilator is flow-triggered and phase cycled (col. 9 lines 48-55 Berthon-Jones '217).

Regarding claim 134, Cotner et al. does not specifically disclose that the ventilator withdraws ventilation support more gradually when the patient is over-ventilated than when the patient is under-ventilated. However, Berthon-Jones teaches that the ventilator withdraws ventilation support more gradually when the patient is over-ventilated than when the patient is under-ventilated (As seen from fig. 6 and col. 11 lines 28-37, when the patient has a cessation of spontaneous effort representing hypoventilation, the ventilator pressure increases rapidly to a

maximum within 4 breaths. However, when the patient resumes normal effort, the respiratory airflow seen as the second graph is at first much higher than normal representing hyperventilation. The ventilator pressure reduces back down to base pressure much slower over 5 breaths. Therefore, the ventilator responded more quickly during hypoventilation). It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the ventilator of Cotner et al. with the function of withdrawing hyperventilation more slowly as taught by Berthon-Jones '217 to provide a smoother more comfortable way of withdrawing support without waking a sleeping patient.

5. Claim 124 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cotner et al. in view of the article entitled "An Adaptive Lung Ventilation Controller" (of record) by Laubscher et al.

Regarding claim 124, Cotner teaches normal inhalation as target value (col. 9 lines 25-35) but doesn't teach that the target value is an alveolar ventilation that takes into account the patient's anatomical or physiologic dead space. However, Laubscher at al. teaches an apparatus (fig. 2) for providing ventilatory assistance wherein the target value "V'ga" is an alveolar ventilation (page 51, col. 2, 4th paragraph) that takes into account the patient's anatomical or physiologic dead space "VD" (page 52 col. 1 paragraph 2 and in formula (2) on page 51 teaches that the target value "V'ga" is a desired ventilation entered by a user as in that takes into account the patient's physiologic dead space VD). It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the ventilator of Cotner et al. with the features of taking physiologic dead space into account for target ventilation as taught by Laubscher et al. to provide more accurate ventilation in people with lung disease

6. Claims 116, 117, and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cotner et al. and Berthon-Jones '217 as applied to claims 115 and 122 above, and further in view of the article entitled "An Adaptive Lung Ventilation Controller" by Laubscher et al.

Regarding claims 116 and 123, the modified Cotner invention teaches all the limitations as claimed. See the rejection of claim 124 above.

Regarding claim 117, the modified Cotner invention teaches all the limitations as claimed. See the rejection of claim 125 above.

7. Claims 126 and 127 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cotner et al. and Berthon-Jones '217 as applied to claims 125 above, and further in view of Berthon-Jones (6, 532, 957 B2), hereinafter Berthon-Jones '957.

Regarding claim 126, Cotner et al. teaches a control mechanism which senses phase by sensing respiratory airflow (fig. 2A and 2B) but does not specifically disclose that said control mechanism determines the phase of the current breathing cycle by relating respiratory airflow and its rate of change to different phases of a normal breathing cycle. However, Berthon-Jones '957 teaches an apparatus (fig. 1b) for providing ventilatory assistance wherein said control mechanism (16) determines the phase of the current breathing cycle by relating respiratory airflow and its rate of change to different phases of a normal breathing cycle (Most clearly seen in fig. 28 and in col. 9 lines 39-41, col. 10 lines 59—67-col. 10 lines 1-8, specifically steps 12-16, Table 1 and Table 2, airflow and it's rate of change are compared to different phases of the breathing cycle through fuzzy logic sets to determine the instantaneous phase). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to

provide the control mechanism of Cotner et al. with the features of determining phase from airflow and airflow derivative as taught by Berthon-Jones '957 to provide a more accurate means to detect the patient's respiratory phase.

Regarding claim 127, the modified Cotner reference teaches that the control mechanism determines the phase of the current breathing cycle by applying a set of fuzzy logic rules. (Most clearly seen in fig. 28 and in col. 9 lines 39-41, col. 10 lines 59—67-col. 10 lines 1-8, specifically steps 12-16, Table 1 and Table 2 of Berthon-Jones '957, airflow and its rate of change are compared to fuzzy logic rules to determine the instantaneous phase.

8. Claims 118-120 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cotner et al. and Berthon-Jones '217 and Laubscher et al, as applied to claims 116 and 117 above, and further in view of Berthon-Jones '957.

Regarding claim 118, the modified Cotner invention teaches all the limitations as claimed. See the rejection of claim 26 above.

Regarding claim 119, the modified Cotner invention teaches all the limitations as claimed. See the rejection of claim 127 above.

Regarding claim 120, the modified Cotner invention teaches that the overall control response (response of amplitude and/or gain of ventilator) is a clipped integral of a function of both of said error signals (col. 9 lines 6-22 Berthon-Jones '217).

Response to Arguments

9. Applicant's arguments filed 1/12/2010 have been fully considered but they are not persuasive.

Regarding applicant's arguments on page 7 lines 7-8, Applicant argues that "there is just one error signal that controls the servo loop" in the Cotner invention. In response, the examiner respectfully disagrees because the end of the 8 second time interval as 1st error signal which is outputted by the timing circuit (col. 6 lines 65-67, col. 7 lines 1-10, col. 9 lines 25-35) and the critical flow limitations as second error signal which signals or indicates a deviation form acceptable inhalation (col. 6 lines 63, col. 8 lines 12-13) are two error signals. As a result of the second error signal indication, the timing circuit begins to count (col. 8 lines 65-67, col. 9 line 1) and the ventilator remains at 2.5cm H20 until the first error signal is sensed in which case the ventilator pressure begins to rise (col. 8 lines 63-64, col. 9 lines 7-20). Therefore, the signal or indication that 8 seconds have elapsed as first error signal, and the signal or indication of a critical flow limitation are two different signals indicating a deviation from proper inhalation and both are used to control the ventilator.

Regarding applicant's arguments on page 7 paragraph 2, applicant alleges that claim 112 defines that "[the error signals] represent the difference (error) between the same desired target value and a measure of ventilation" and that the error signals "control the servo." In addition, on page 7, paragraph 3, applicant argues that there is only one error signal that "controls an increase in pressure." However, the arguments are irrelevant because the definition given for "error signal", the limitation that the ventilator is a "servo", and the limitation that the error signals increase the ventilator pressure are not supported by the claim 112 language.

Regarding applicant's arguments on page 8, Applicant states in paragraph one, in an interpretation of the invention of Cotner, that "The other input to detector 24 is the output from dynamic reference tracking circuit 25, which is a filter. It appears from the middle paragraph in column 6 that this circuit derives the average value of the variable over recent breaths. This means that detector 24 (which causes the timing circuit that represents an "error" to be triggered if the output of the detector indicates the absence of a breath for eight seconds) compares the instantaneous value of the variable with the average value. Every time the patient breathes, the output of the detector 24 goes high because there is a large departure from the average value." In response, the examiner respectfully disagrees with this interpretation as it appears that applicant has misunderstood the invention of Cotner. Cotner does not detect inhalation or the absence thereof using a comparison between instantaneous ventilation and an average value. Cotner detects inhalation and the absence thereof by comparing the instantaneous ventilation with the signal output "R" of the dynamic reference tracking circuit. The dynamic reference tracking circuit comprises 2 capacitors tied to ground (col. 6 lines 23-25) to cause a time delay. Thus, the signal "R" is a delayed version of the filtered airflow signal "M", not an average. As seen from figs. 2A and 2B, when signal "M" falls below signal "R", the differential operational amplifier goes logical one to indicate the start of inhalation. When signal "M" rises above signal "R" the differential operational amplifier goes logical 0 indicating the end of inhalation and the beginning of exhalation. The ventilator increases in pressure in response to signal "M" failing to fall below "R" as a result of a critical flow limitation for a duration of 8 seconds. The ventilator is kept at 2.5cm H20 until 8 seconds have elapsed. But as a result of the critical flow limitation indication as 2nd error signal, which is indicated by the behavior of signals "M" and "R" and

which is represented in fig. 3 at letter "C", and as a result of the timing circuit indicating the end of the 8 second interval, the ventilator rises in pressure. Thus there are two error signals both of which function to control a ventilator response.

Conclusion

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to LATOYA LOUIS whose telephone number is (571)270-5337. The examiner can normally be reached on Monday-Friday, 9:30am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine YU can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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3/11/2010

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